UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

ARACELY OREGON, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, Defendant.	No. 1:21-cv-01092-DAD-BAK ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION TO DISMISS (Doc. No. 6)

This matter is before the court on defendant Boston Scientific Corporation's motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6). (Doc. No. 6.) Pursuant to General Order No. 617 addressing the public health emergency posed by the COVID-19 pandemic, defendant's motion was taken under submission on the papers. (Doc. No. 7.) For the reasons explained below, the court will grant in part and deny in part defendant's motion to dismiss.[1]

[1] The undersigned apologizes for the excessive delay in the issuance of this order. This court's overwhelming caseload has been well publicized and the long-standing lack of judicial resources in this district long-ago reached crisis proportion. While that situation was partially addressed by the U.S. Senate's confirmation of a district judge for one of this court's vacancies on December 17, 2021, another vacancy on this court with only six authorized district judge positions was created on April 17, 2022. For over twenty-two months the undersigned was left presiding over approximately 1,300 civil cases and criminal matters involving 735 defendants. That situation

BACKGROUND

Plaintiff filed her complaint in this action on July 15, 2021. (Doc. No. 1.) Therein, plaintiff alleges the following. Defendant Boston Scientific Corporation designed, manufactured, marketed, and distributed the Obtryx, a pelvic mesh device meant to treat stress urinary incontinence. (*Id.* at ¶ 7.) Defendant's pelvic mesh products, including the Obtryx, contain monofilament polypropylene mesh. (*Id.* at ¶ 8.) Synthetic materials like polypropylene are known to induce an acute inflammatory response, followed by chronic inflammatory responses and foreign body reactions. (*Id.* at ¶ 14.) A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. (*Id.*) When pelvic mesh products, including the Obtryx, are inserted in the female body according to the manufacturer's instructions, they create a non-anatomic condition with mechanical mismatch in the pelvis, leading to a multitude of injuries including:

> the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic, vaginal, groin and leg pain, recurrence, worsening incontinence, chronic dyspareunia, injury or irritation of the obturator, pudendal and other pelvic nerves, injury or irritation of the muscles and soft tissues of the pelvis, wound infection, rejection of the mesh, tissue necrosis and irritation, sexual dysfunction, urinary and defecatory dysfunction, vaginal scarring, wound healing problems, injury to urethra, pelvic abscess formation, hematoma, risk of infection, and/or the need for additional surgeries, among others.

(*Id.* at ¶ 18.) As a result, defendant's product is not suitable for its intended application as a permanent prosthetic implant for stress urinary incontinence in women. (*Id.*) Moreover, defendant has not adequately studied the extent of the risks associated with its pelvic mesh products. (*Id.* at ¶ 35.) In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks. (*Id.*) Defendant knew or should have known about the risks and complications associated with their pelvic mesh products. (*Id.* ¶ 39.)

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resulted in the court not being able to issue orders in submitted civil matters within an acceptable period of time and continues even now as the undersigned works through the predictable backlog. This has been frustrating to the court, which fully realizes how incredibly frustrating it is to the parties and their counsel.

Specifically, defendant knew or should have known that the Obtryx unreasonably exposed patients to the risk of serious harm, while conferring no benefit compared to available feasible alternatives that do not involve the same risks. (*Id.* at ¶ 40.) Nevertheless, the Obtryx has been and continues to be marketed by defendant to the medical community as a safe, effective, and reliable medical device, implanted by safe, effective, and minimally invasive surgical techniques, and as safe and more effective than comparable and available alternative treatments of stress urinary incontinence. (*Id.* at ¶ 50.) Defendant should have warned physicians and patients regarding these risks to the extent they were known or knowable. (*Id.* at ¶ 47.) While some of the problems associated with the Obtryx were made known to physicians, the magnitude and frequency of these problems were not disclosed and were in fact hidden from physicians. (*Id.* at ¶ 52.) Therefore, defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Obtryx and the aftercare of patients implanted with the product. (*Id.* at ¶ 61.)

On or about November 5, 2009, plaintiff was implanted with the Obtryx. (*Id.* at ¶ 73.) The Obtryx was intended to treat plaintiff for stress urinary incontinence. (*Id.* at ¶ 80.) Soon thereafter, plaintiff began experiencing severe pelvic pain and associated dyspareunia pain. (*Id.* at ¶ 77.) Ten years later, on October 9, 2019, plaintiff underwent a revision surgery and partial mesh removal. (*Id.* at ¶ 79.) Plaintiff was significantly and permanently injured as a result of the defective pelvic mesh device. (*Id.* at ¶ 1.) Plaintiff developed multiple medical conditions that were caused by the implant, including groin pain, pain with sitting, tailbone pain, de novo dyspareunia, pelvic pain, anorectal pain, painful bladder filling, constipation, clitoral numbness, impaired mobility, perineal pain, bladder outlet obstruction, urge incontinence, obstructive voiding, urinary tract infections, and hematuria. (*Id.* at ¶ 85.) Plaintiff reasonably relied upon defendant's statements in deciding to get the Obtryx implant. (*Id.* at ¶ 69.) Had defendant properly disclosed the risks associated with the Obtryx, plaintiff would not have used it. (*Id.* at ¶ 89.)

Based on the foregoing plaintiff alleges the following four causes of action: (1) strict liability — failure to warn; (2) strict liability — manufacturing defect; (3) negligence — design

defect, manufacturing defect, and failure to warn; and (4) negligent misrepresentation. (Doc. No. 1 at 23–27.)

On September 21, 2021, defendant filed the pending motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (Doc. No. 6.) One October 6, 2021, plaintiff filed her opposition to the pending motion. (Doc. No. 9.) On October 12, 2021, defendant filed its reply thereto. (Doc. No. 10.)

LEGAL STANDARDS

A. Motion to Dismiss Pursuant to Rule 12(b)(6)

The purpose of a motion to dismiss pursuant to Rule 12(b)(6) is to test the legal sufficiency of the complaint. *N. Star Int'l v. Ariz. Corp. Comm'n*, 720 F.2d 578, 581 (9th Cir. 1983). "Dismissal can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A claim for relief must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Though Rule 8(a) does not require detailed factual allegations, a plaintiff is required to allege "enough facts to state a claim for relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. In determining whether a complaint states a claim on which relief may be granted, the court accepts as true the allegations in the complaint and construes the allegations in the light most favorable to the plaintiff. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *Love v. United States*, 915 F.2d 1242, 1245 (9th Cir. 1989). It is inappropriate to assume that the plaintiff "can prove facts that it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

"Dismissal without leave to amend is proper if it is clear that the complaint could not be saved by amendment." *Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1051 (9th Cir. 2008). To the extent that the pleadings can be cured by the allegation of additional facts, courts will generally

grant leave to amend. *Cook, Perkiss and Liehe, Inc. v. N. Cal. Collection Serv. Inc.*, 911 F.2d 242, 247 (9th Cir. 1990) (citations omitted).

B. Pleading Fraud Pursuant to Rule 9(b)

A complaint alleging fraud must also satisfy heightened pleading requirements. Fed. R. Civ. P. Rule 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."). "Fraud can be averred by specifically alleging fraud, or by alleging facts that necessarily constitute fraud (even if the word 'fraud' is not used)." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (citing *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1107 (9th Cir. 2003)). "When an entire complaint, or an entire claim within a complaint, is grounded in fraud and its allegations fail to satisfy the heightened pleading requirements of Rule 9(b), a district court may dismiss the complaint or claim." *Vess*, 317 F.3d at 1107.

Under Rule 9(b), the "circumstances constituting the alleged fraud [must] be 'specific enough to give defendants notice of its particular misconduct . . . so they can defend against the charge and not just deny that they have done anything wrong.'" *Kearns*, 567 F.3d at 1124 (citing *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)). To satisfy the particularity standard of Rule 9(b), the plaintiff must allege the "'who, what, when, where, and how' of the misconduct charged." *Id.* (citing *Vess*, 317 F.3d at 1106).

DISCUSSION

A. Strict Liability Failure to Warn Claim

Plaintiff's first cause of action alleges that defendant failed to adequately warn of the risks associated with the Obtryx. (Doc. No. 1 at 23.)

Although California law permits a strict liability failure to warn theory of liability, it also provides that failure to warn in the context of prescription medical devices must be read in tandem with California's "learned intermediary" doctrine. *Hannan v. Bos. Sci. Corp.*, No. 4:19-cv-08453-PJH, 2020 WL 2128841, at *7 (N.D. Cal. May 5, 2020); *Bigler-Engler v. Breg, Inc.*, 7 Cal. App. 5th 276, 319 (2017) (noting that the learned intermediary doctrine applies to implanted medical devices). The learned intermediary doctrine provides that in the case of prescription

drugs and medical devices, the duty to warn "runs to the physician, not the patient." *Id.* (citing *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1116 (1996)); *see also Webb v. Special Electric Co., Inc.*, 63 Cal. 4th 167, 187 n.10 (2016). A manufacturer discharges this duty to warn by "provid[ing] adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient." *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 990–91 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659 (9th Cir. 2004). The learned intermediary doctrine "applies when drugs or medical devices are supplied in the context of the doctor-patient relationship[,]" *Webb*, 63 Cal. 4th at 187 n.10, but "does not apply to medical devices . . . which require the patient to use and apply the medical device themselves." *Bigler-Engler*, 7 Cal. App. 5th at 319. Where the doctrine applies, a plaintiff who asserts a claim "based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017).

In the pending motion to dismiss, defendant argues that plaintiff has only alleged that defendant owed a duty to provide warnings to plaintiff and the public. (Doc. No. 6-1 at 8.) Defendant thus argues that "to the extent they are predicated on warnings to her and the public, Plaintiff's failure-to-warn claims are barred by the learned intermediary doctrine and should be dismissed as a matter of law." (*Id.*)

In her opposition to the pending motion, plaintiff argues her complaint alleges that defendant "did not provide appropriate, if any, warnings" and that plaintiff's doctors therefore "could not have transmitted appropriate warnings because [defendant] failed to provide the medical community with such warnings." (Doc. No. 9 at 5.) Plaintiff contends that under the factual allegations of her complaint, "the 'intermediary' was not provided, and therefore did not possess, adequate warnings and notice of risk such that it would have been able to provide Plaintiff Oregon with learned information, advice, or knowledge of the risks." (*Id.*)

In its reply, defendant responds that while the allegations of plaintiff's complaint "confirms that [defendant] provided instructions and information about risks to physicians," plaintiff does not identify "sufficient factual allegations as to how or why the warnings provided

by [defendant] are purportedly inadequate in this particular case." (Doc. No. 10 at 5.) Specifically, defendant contends that plaintiff's allegations "fail to identify which warnings were provided to her physician, and how those specific warnings were insufficient." (*Id.*)

The court recognizes that "[m]erely stating that the Defendants failed to 'adequately warn' of [the alleged injury] is a bare legal conclusion" and would be insufficient to state a cognizable failure to warn claim in this context. *See Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1161 (E.D. Cal. 2019). Here, however, plaintiff has alleged in her complaint that defendant failed to warn her physicians about the specific potential risks posed by the Obtryx. For example, plaintiff alleges defendant's "failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to" the Obtryx's propensities to contract inside the body, the Obtryx's propensities for degradation, the risk of chronic inflammation resulting from the Obtryx, the need for corrective or revision surgery to adjust or remove the Obtryx, and a long list of other specific potential harms that plaintiff alleges were not adequately shared by defendant with her treating physicians. (Doc. No. 1 at ¶ 55.) Moreover, plaintiff has alleged that, in spite of these risks, defendant deliberately represented that the product was safe and effective and continued to market its use "to *physicians* and patients, including Mrs. Oregon and [her] healthcare providers, without adequate warnings." (*Id.* at ¶ 87) (emphasis added). Lastly, plaintiff has alleged causation in that "[h]ad Defendant properly disclosed the risks associated with [the Obtryx], Mrs. Oregon would not have used it." (*Id.* at ¶ 89) (*see also* ¶ 98 ("Mrs. Oregon would not have consented to use [the Obtryx] had Defendant given adequate warnings to her and her implanting physicians.") Based on these allegations set forth in plaintiff's complaint, the court concludes that plaintiff has adequately alleged a strict liability failure to warn claim against defendant.

The district court decisions in *Zetz v. Bos. Sci. Corp.*, 398 F. Supp. 3d 700 (E.D. Cal. 2019) and *Hannan*, 2020 WL 2128841 support this conclusion. In *Zetz* and *Hannan*, the district courts concluded that allegations similar to those appearing in plaintiff's complaint here sufficiently stated a failure to warn claim. For example, the plaintiffs in *Zetz* alleged that Boston Scientific "knowingly provided incomplete and insufficient training and information to

physicians regarding the use of the Obtryx and the aftercare of patients implanted with the Obtryx." *Zetz*, 398 F. Supp. 3d at 707. The plaintiffs in *Zetz* also alleged "[t]he risk of serious injuries was known or should have been known to Defendants, but in spite of these risks, Defendants deliberately concealed these risks and, instead, represented that the product was safe and effective and continued to market the Obtryx to physicians and patients, including Plaintiffs, without adequate warnings." *Id.* Similarly, in *Hannan*, the plaintiffs alleged that defendant "failed to properly and adequately warn and instruct the Plaintiff and/or her health care providers as to the risks and benefits of Boston Scientific's Pelvic Mesh Products." *Hannan*, 2020 WL 2128841, at *7. The plaintiffs in *Hannan* further alleged that "Boston Scientific failed to provide adequate warning or instruction via its 'Directions for Use of the Obtryx, Physician training, and marketing to Plaintiff or her implanting physicians and health care providers.'" *Id.*

The allegations in *Zetz* and *Hannan* are remarkably similar to the allegations presented by plaintiff in her complaint in this action. For the same reasons stated in those decisions, the undersigned concludes that plaintiff has adequately alleged that defendant failed to warn her physicians of the potential risks associated with the Obtryx and that this alleged failure to warn impacted plaintiff's decision to undergo treatment with the Obtryx, thus contributing to her injuries. Therefore, defendant's motion to dismiss plaintiff's strict liability failure to warn claim will be denied. However, to the extent that plaintiff's failure to warn claim is based upon an asserted duty owed to her personally or to the public generally, instead of to her physician, those claims will be dismissed with prejudice.

B. Strict Liability Manufacturing Defect Claim

Plaintiff's second cause of action is a manufacturing defect claim brought pursuant to a strict liability theory of liability. (Doc. No. 1 at 24.) Under California law, a manufacturing defect "is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Barker v. Lull*, 20 Cal. 3d 413, 429 (1978). The manufacturing defect theory posits that "a suitable design is in place, but that the manufacturing process has in some way deviated from that design." *In re Coordinated Latex Glove Litig.*, 99 Cal. App. 4th 594, 613 (2002).

In its motion to dismiss, defendant argues that plaintiff has "failed to plead any facts supporting a manufacturing defect claim." (Doc. No. 6-1 at 9.) Defendant contends that plaintiff merely "points to vague allegations of design defect to support her manufacturing defect claim," for example that the polypropylene mesh was unsuitable for use and the Obtryx implanted in her was not inert, but rather contracted and degraded upon implant. (*Id.*) Defendant asserts that these conclusory allegations do not sufficiently allege how the Obtryx implanted in plaintiff deviated from defendant's intended result or from other identical units of the same product line. (*Id.*)

In her opposition, plaintiff directs the court to the allegations of her complaint that "[t]he Mesh Product[] was designed to be permanently implanted into a woman's body yet the product changes: it contracts over time which can pull or compress nerves key for sexual function, mobility, bowel and bladder function." (Doc. No. 9 at 7.) According to plaintiff, "[t]hese changes occurred and the Mesh Product implanted in Plaintiff degraded on explant with findings of chronic inflammation." (*Id.*)

In its reply, defendant points out that the device's material is part of its intended design and that plaintiff's allegations in fact suggest a design defect claim, not a manufacturing defect claim. (Doc. No. 10 at 6.) Defendant concludes that plaintiff essentially "merely alleges that her device acted just like the other devices of its kind." (*Id.*)

The court finds defendant's arguments persuasive. Simply put, plaintiff has not alleged any facts supporting a manufacturing defect claim. If plaintiff intends to allege a manufacturing defect claim, she must make allegations identifying and explaining how the Obtryx either deviated from defendant's intended result/design or how the product deviated from other identical products. *See Barker*, 20 Cal. 3d at 429. Plaintiff has not done so in her complaint and has failed to allege how the particular product implanted in her is different from all the other products like it. Accordingly, the court will grant defendant's motion to dismiss plaintiff's strict product liability claim to the extent that it is predicated on an alleged manufacturing defect.

In addition, to the extent plaintiff intended to allege a strict liability *design defect* claim, she has not done so in her complaint. However, even if she had alleged such a claim, California law precludes strict liability predicated on design defects with respect to manufacturers of

prescription medical devices. *See Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173, 182 (2013) (recognizing "an exemption from design defect strict products liability for all implanted medical devices that are available only through the services of a physician"). Rather, under California law, "the appropriate test for determining a prescription [medical device] manufacturer's liability for a design defect involves an application of the ordinary negligence standard." *Id.*

C. Negligence Claims

Plaintiff's third cause of action is a negligence claim in which plaintiff asserts that defendant had a duty to act reasonably and to exercise ordinary care in "researching, manufacturing, licensing, fabricating, designing, labeling, distributing, supplying, promoting, selling, marketing, warranting, packaging and advertising" the Obtryx. (Doc. No. 1 at ¶ 110.) Plaintiff also alleges that defendant had a duty to warn or instruct plaintiff or her health care providers. (*Id.* at ¶ 112.) Thus, plaintiff appears to be asserting design defect, manufacturing defect, and failure to warn theories, all sounding in negligence. *See Hannan*, 2020 WL 2128841, at *7 (finding the same based on similar allegations).

A negligence claim under California law requires plaintiff to allege that defendant "owed [plaintiff] a legal duty, breached the duty, and that the breach was a proximate or legal cause of [plaintiff's] injury." *Gonzalez v. Autoliv ASP, Inc.*, 154 Cal. App. 4th 780, 793 (2007); *Mendoza v. City of Los Angeles*, 66 Cal. App. 4th 1333, 1339 (1998). Moreover, "[i]n the context of a products liability lawsuit, '[u]nder a negligence theory, a plaintiff must also prove . . . that the defect in the product was due to negligence of the defendant.'" *Id.* (quoting *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479 (2001)) (quotations omitted).

In its motion to dismiss, defendant argues that plaintiff's negligence claim consists of nothing more than a recitation of the elements and contends that "[a]t no point does Plaintiff identify any negligent conduct by [defendant], nor does she identify how [defendant's] alleged breach proximately caused her alleged injuries." (Doc. No. 6-1 at 10.)

In her opposition, plaintiff does not meaningfully refute defendant's arguments. Rather, plaintiff merely cites the allegations from her complaint. (Doc. No. 9 at 3–4.)

The court will address each potential theory of negligence (design defect, manufacturing defect, failure to warn) in turn below.

1. Design Defect

Generally, the "test of negligent design involves a balancing of the likelihood of harm to be expected from a product with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm." *Merrill*, 26 Cal. 4th at 479. "Even if a manufacturer has done all it reasonably could have done to warn about a risk or hazard related to a product's design, a reasonable person could conclude that the magnitude of the reasonably foreseeable harm as designed outweighed the utility of the product as designed." *Tucker v. Wright Med. Tech.*, No. 4:11-cv-03086-YGR, 2013 WL 1149717, at *7 (N.D. Cal. Mar. 19, 2013) (citing *Chavez v. Glock, Inc.*, 207 Cal. App. 4th 1283, 1305 (2012)). This analysis is akin to a risk-benefit test. *Id.* at *8.

Here, plaintiff has alleged "a broad variety of potential defects with defendant's pelvic mesh products." *Hannan*, 2020 WL 2128841, at *10. For example, plaintiff alleges that the design of the Obtryx caused it to be inserted into an area of the body that is blood vessel rich, which leads to the body adhering to the mesh, "causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries" including "blood loss and vascular damage, permanent nerve injury, and associated chronic, intractable neuropathic pain." (Doc. No. 1 ¶ 54.) Plaintiff further alleges that "[t]he use of polypropylene in the Mesh Product and the immune reactions that result from such material" cause "adverse reactions and injuries, including but not limited to, painful recurrent erosions and associated intractable pain." (*Id.*) Another example—though there are at least six others set forth in plaintiff's complaint—is that plaintiff alleges that "the propensity of the Mesh Product to contract or shrink inside the body" causes surrounding tissue to erode "because of mechanical mismatch between soft tissues and the mesh," which results in serious, permanent injury. (*Id.*) Lastly, plaintiff alleges that "[t]he FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks." (*Id.* at ¶ 27) (*see also id.* at ¶ 51 ("SUI can also be corrected by safer alternative designs of polypropylene mesh that do not

present the same frequency or severity of risks as [does] [the Obtryx].")).

The court concludes that plaintiff's allegations are sufficient to state a claim for negligent design defect because she has identified several aspects of the Obtryx that are purportedly defectively designed, and she has alleged that the potential risk of harm posed by those alleged defects outweighed any benefits offered by the product. *See Hannan*, 2020 WL 2128841, at *10.

Accordingly, defendant's motion to dismiss plaintiff's negligent design defect claim will be denied.

2. Manufacturing Defect

The court's reasoning and conclusion reached as to plaintiff's strict liability manufacturing defect cause of action apply equally to her negligent manufacturing defect claim. *See Marroquin*, 367 F. Supp. 3d at 1164 (finding the strict liability manufacturing defect analysis applied equally to the analysis of the plaintiff's negligent manufacturing defect claim); *Hannan*, 2020 WL 2128841, at *9 (same). Plaintiff has not alleged any facts supporting her contention that the Obtryx implanted in her was negligently manufactured. Therefore, plaintiff has failed to adequately allege a negligent manufacturing defect claim.

3. Failure to Warn

For the reasons stated above with respect to plaintiff's strict liability failure to warn claim, the court also concludes that plaintiff has adequately alleged a negligent failure to warn claim. Specifically, in her complaint, plaintiff has identified the facts and subjects that defendant failed to warn her physicians about. The district courts in *Hannan* and *Zetz* reached the same conclusion based on nearly identical allegations. *See Hannan*, 2020 WL 2128841, at *8; *Zetz*, 398 F. Supp. 3d at 707. Therefore, as in *Hannan*, this court concludes that plaintiff has "sufficiently alleged that Boston Scientific had a duty to warn plaintiff's physicians and failed to do so." *Id.*

Furthermore, plaintiff has alleged that defendant's negligence directly and proximately caused her injuries. (Doc. No. 1 at ¶¶ 90, 101.) While a plaintiff of course cannot allege proximate cause in a mere conclusory fashion, here plaintiff's complaint alleges specific facts in support of her failure to warn claim. Namely, plaintiff has alleged that she suffered from the

same specified types of harms and injuries (*id.* at ¶ 85) that are commonplace with this particular mesh product. Indeed, in her complaint plaintiff points to several examples from medical literature that illustrate how her alleged injuries can be caused by defective mesh products like the Obtryx. (*See generally id.* at ¶¶ 22–46.) In addition, plaintiff asserts that had defendant "properly disclosed the risks and the magnitude of risk including life-altering pain associated with the [Obtryx] compared with safer alternative procedures and safer alternative designs, [plaintiff] and her physicians would not have used it." (*Id.* at ¶ 134.) At the pleading stage, the court deems these alleged facts sufficient to support plaintiff's claim that defendant's failure to warn caused her harm.

Thus, construing all of plaintiff's allegations in the light most favorable to plaintiff—as it must when considering a motion to dismiss—the court concludes that plaintiff has sufficiently alleged that defendant negligently failed to warn her physicians of the potential harms associated with the use of the Obtryx product. Defendant's motion to dismiss plaintiff's negligent failure to warn claim will therefore be denied.

D. Negligent Misrepresentation

Plaintiff's fourth cause of action alleges negligent misrepresentation. (Doc. No. 1 at 27.) The elements of negligent misrepresentation are: "(1) a misrepresentation of a past or existing material fact, (2) without reasonable grounds for believing it to be true, (3) with intent to induce another's reliance on the fact misrepresented, (4) ignorance of the truth and justifiable reliance thereon by the party to whom the misrepresentation was directed, and (5) damages." *Fox v. Pollack*, 181 Cal. App. 3d 954, 962 (1986). Because negligent misrepresentation is rooted in fraud, plaintiff must meet the pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. *See Zetz*, 398 F. Supp. 3d at 713. "To plead fraud with particularity as required by Rule 9(b), a complaint 'must identify the who, what, when, where, and how of the misconduct charged, as well as what is false or misleading about the purportedly fraudulent statement, and why it is false.'" *Id.* (quoting *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 964 (9th Cir. 2018)). "Additionally, when the defendant is an entity, a complaint generally must also identify the person who made the false representations on behalf of the entity." *Id.* (citing *United States*

ex. Lee v. SmithKline Beecham, 245 F.3d 1048, 1051 (9th Cir. 2001); *White v. J.P. Morgan Chase, Inc.*, 167 F. Supp. 3d 1108, 1115 (E.D. Cal. 2016)).

In its motion to dismiss, defendant argues that plaintiff has failed to allege the "who, what, when, where, and how" of any purported misrepresentation. (Doc. No. 6-1 at 12.) Instead, defendant asserts that plaintiff merely "generally claims that Boston Scientific made misrepresentations and concealments about the safety and efficacy of the Obtryx device." (*Id.*)

In her opposition, plaintiff points to the allegations in her complaint that defendant "willfully deceived the Plaintiff, their prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general as to the health risks and consequences of the use of the mesh product." (Doc. No. 9 at 10.) Plaintiff notes that she has alleged "the misrepresentations by Defendants regarding the safety and efficacy of the mesh product were made with the intention of inducing reliance and inducing the purchase and implantation of the product." (*Id.*) Moreover, plaintiff contends that she has alleged when the misrepresentations took place (November 5, 2009), where they took place (California), and how they took place ("Defendant conducted a sales and marketing campaign to promote the sale of the mesh using various means, including the media, to the medical, scientific, pharmaceutical and health care communities, to the general public, and to patients themselves"). (*Id.* at 11.) According to plaintiff, "[t]hese allegations more than demonstrate the plausibility of [defendant's] fraud and misrepresentations." (*Id.*)

In its reply, defendant argues that plaintiff's "allegations are nothing more than broad statements that lack the necessary specificity under Rule 9(b)." (Doc. No. 10 at 8.) For example, defendant points out that while plaintiff identifies the "who" as Boston Scientific Corporation, she has not identified "the person who made the false representations on behalf of the entity.'" (*Id.*) (quoting *Marroquin*, 367 F. Supp. 3d at 1166.) Moreover, defendant asserts that plaintiff fails to sufficiently allege the "how" and "where" aspects of her claim under the Rule 9(b) standard because "she does not specify what brochure, marketing material, or other document or representation Plaintiff relied on, nor where she was when she read, heard, or saw the purported misrepresentation." (*Id.*) Lastly, defendant argues that plaintiff's complaint does not adequately

allege her reliance on any purported misrepresentation because "[t]he allegations in the Complaint do not plausibly suggest that she relied on anything other than her physician's judgment and assessment that the mesh device was appropriate for her in her course of treatment." (*Id.* at 9.) According to defendant, if plaintiff solely relied on her physician to prescribe the product, she could not have relied personally on any representations by defendant. (*Id.* at 8–9.) (quoting *Marroquin*, 367 F. Supp. 3d at 1167.)

The court concludes that plaintiff's allegations do not meet the heightened pleading requirements of Rule 9(b). "Rule 9(b) demands that the circumstances constituting the alleged fraud 'be specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong.'" *Kearns*, 567 F.3d at 1124 (quoting *Bly-Magee*, 236 F.3d at 1019). "Generalized allegations of misrepresentation, concealment, and unspecified sales and marketing materials lack sufficient particularity under Rule 9(b)." *Zetz*, F. Supp. 3d at 707. In her complaint, plaintiff has not alleged any specifics concerning defendant's asserted negligent misrepresentation. Rather, throughout her complaint, plaintiff merely repeatedly alleges that "[i]n doing the acts herein, the Defendant acted with oppression and/or fraud and/or malice in demonstrating a conscious disregard for the rights and safety of Mrs. Oregon and others. Said wrongful conduct was done with advance knowledge and or authorization and/or was ratified by an officer, director and/or managing agent of the Defendant and warrants the imposition of an award of punitive damages." (Doc. No. 1 at ¶¶ 102, 107, 119, 136.) Such conclusory and elemental allegations are insufficient to meet the heightened pleading standards of Rule 9(b), which requires that the "who, what, when, where, and how" of the misrepresentation be supported by specifically alleged facts.

Accordingly, defendant's motion to dismiss plaintiff's fourth claim for negligent misrepresentation will be granted.

E. Punitive Damages

Finally, the parties dispute whether plaintiff has adequately alleged her causes of action in a manner that supports a claim seeking punitive damages. (Doc. Nos. 6-1 at 12; 9 at 11.)

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"Under California law, punitive damages require a showing by clear and convincing evidence that a defendant acted with oppression, fraud, or malice." *Dudgeon v. County of Sonoma*, No. 19-cv-05615-JCS, 2021 WL 5407519, at *16 (N.D. Cal. Nov. 18, 2021) (citing Cal. Civ. Code § 3294(a)). Where a plaintiff proves that the defendant has been guilty of fraud or malice, that plaintiff may recover punitive damages. Cal. Civ. Code § 3294(a). However, "a *corporate entity* cannot commit willful and malicious conduct; instead, 'the advance knowledge and conscious disregard, authorization, ratification or act of oppression, fraud, or malice must be on the part of an officer, director, or managing agent of the corporation.'" *In re Yahoo! Inc. Customer Data Sec. Breach Litig.*, 313 F. Supp. 3d 1113, 1147-48 (N.D. Cal. 2018) (emphasis added) (quoting Cal. Civ. Code § 3294(b)); *see also Taiwan Semiconductor Mfg. Co. v. Tela Innovations, Inc.*, No. 14-cv-00362-BLF, 2014 WL 3705350, at *6 (N.D. Cal. July 24, 2014) ("[A] company simply cannot commit willful and malicious conduct—only an individual can.")

Here, plaintiff has not sufficiently alleged that defendant or any of its employees or corporate leaders acted with oppression, fraud, or malice. *See Fischer v. Bos. Sci. Corp.*, No. 2:19-cv-02106-JVS-DFM, 2020 WL 2300138, at *4 (E.D. Cal. Mar. 25, 2020) (concluding that plaintiff's punitive damages claims could not stand on their own because her "fraud based claims failed and were dismissed" as generalized and conclusory). Accordingly, the court will also grant defendant's motion to dismiss plaintiff's claim for punitive damages.

F. Leave to Amend

Plaintiff requests leave to amend her complaint. (Doc. No. 9 at 12.) Generally, "[c]ourts are free to grant a party leave to amend whenever 'justice so requires,' and requests for leave should be granted with 'extreme liberality.'" *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 972 (9th Cir. 2009). There are several factors a district court considers in whether to grant leave to amend, including undue delay, the movant's bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party, and futility. *Brown v. Stored Value Cards, Inc.*, 953 F.3d 567, 574 (9th Cir. 2020) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Of the factors from *Foman*, the court should consider

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prejudice to the opposing party in particular. *Id.*; *Eminence Cap., LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).

Here, there is no indication that allowing amendment would be prejudicial to defendant, and defendant makes no comment to that effect. There is also no indication that plaintiff has acted in bad faith, and there have been no other attempts to cure noted pleading deficiencies by previously allowed amendments. Plaintiff will therefore be granted leave to amend.

CONCLUSION

For all of the reasons set forth above:

1. The court denies in part and grants in part defendant's motion to dismiss (Doc. No. 6) as follows:
   a. The court grants defendant's motion to dismiss plaintiff's strict liability manufacturing defect claim, negligent manufacturing defect claim, negligent misrepresentation claim, and claim for punitive damages;
   b. The court denies defendant's motion to dismiss plaintiff's strict liability failure to warn claim, negligent failure to warn claim, and negligent design defect claim; and
2. Within twenty-one (21) days of service of this order, plaintiff shall file any amended complaint or notify the court of her intention to proceed only on the claims asserted in her original complaint found to be cognizable in this order.

IT IS SO ORDERED.

Dated: **May 20, 2022**

Dale A. Drozd
UNITED STATES DISTRICT JUDGE